K121151

510(k) Summary

Pro-Link Cervical Spacer System

NOV 16 2012

Submitted By:

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510(k) Contact:

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Date Prepared: April 13th, 2012

Trade Name: Pro-Link Cervical Spacer

Classification: OVE, 21 CFR 888.3080, Class II, Intervertebral Body Fusion Device

Predicate Device:

The Small Plateau (Plateau-C) Spacer System (K111835)
LDR Spine Cervical Interbody Fusion System (K113559)
Globus Coalition (K083389)
RSB Spine Interplate (K081194)

Device Description:

The PRO-LINK Cervical Spacer System is intended to serve as a stand-alone intervertebral body fusion device. The system is available in a range of sizes and footprints to suit the individual pathology and anatomical conditions of the patient. The implant is hollow to permit packing with autogenous bone graft to help promote fusion. It includes two pockets to permit placement of titanium bone screws (Ti 6Al-4V ELI) to provide internal fixation while a titanium lock plate (Ti 6Al-4V ELI) prevents screw back out.

Intended Use of the Device:

The Pro-Link Cervical Spacer System is intended to be used with the screws provided and requires no additional supplementary fixation.

The Pro-Link System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. It is to be used in patients who have had at least six weeks of non-operative treatment. This device is intended to be used with autogenous bone graft.

Technological Characteristics:
The Pro-Link Cervical Spacer System is substantially equivalent to the predicate systems in terms of design, materials, and indications for use.

Material:

The PRO-LINK Cervical Spacer System is manufactured from implantable grade PEEK-Optima LT1 per ASTM F2026, incorporates tantalum markers per ASTM F560, and implantable grade titanium (Ti 6Al-4V ELI) per ASTM F136.

Performance Data:
Static and dynamic torsion and compression testing in accordance with ASTM F2077 was presented to demonstrate the substantial equivalency of the Pro-Link Cervical Spacer System.

Conclusion:

The Pro-Link Cervical Spacer System was shown to be substantially equivalent to the previously cleared devices in indications for use, design, function, and materials used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Life Spine, Incorporated
% Mr. Randy Lewis
Regulatory Affairs and Quality Assurance Manager
2401 West Hassell Road, Suite 1535
Hoffman Estates, Illinois 60169

Letter Dated: November 16, 2012

Re: K121151
Trade/Device Name: Pro-Link Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: OVE
Dated: October 11, 2012
Received: October 11, 2012

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Laurence D. Coyne

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K 121 151

Device Name: Pro-Link Cervical Spacer System

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Prescription Use _x_ (Part 21 CFR 801 Subpart D)	And/Or	Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number K121151